IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LIFEPORT SCIENCES LLC, Plaintiff, v. ENDOLOGIX, INC., Defendant.	C.A. No. 12-cv-01791 GMS
LIFEPORT SCIENCES LLC, Plaintiff, v. W.L. GORE & ASSOCIATES, INC., Defendant.	C.A. No. 1:12-cv-01792 GMS

DECLARATION OF JAMES MOORE, JR., Ph.D.

I provide the following Declaration in support of Lifeport Sciences LLC in the above captioned matters.

1. Briefly, my educational background and experience are as follows. I earned a bachelor degree, a master of science degree, and a Ph.D in Mechanical Engineering from the Georgia Institute of Technology. I received my Ph.D in 1991. Among other topics, my career has focused on researching and designing medical devices, including stent-based devices similar to those at issue in this case. Presently, I am the Bagrit and Royal Academy of Engineering Chair in Medical Device Design at Imperial College in London. A copy of my curriculum vitae is attached as Exhibit A.

I. TECHNOLOGY

2. The patents-in-suit are directed to life-saving innovations for the repair of aneurysms. Many of the patents teach the first generation of stent-grafts deployed with minimally invasive procedures to effectively create a new vessel wall covering the aneurysm, thus eliminating the potential for the aneurysm to burst. The other patents teach innovative technologies to ensure the clinically desirable delivery and deployment of the stent-graft within the damaged vessel wall. In my opinion, a person of ordinary skill in the art would have been either (i) a physician specializing in radiology, cardiology, cardiovascular surgery, percutaneous transluminal coronary angioplasty or some related discipline, with training, experience and/or familiarity applying principles of mechanical or biomedical engineering or materials science, or (ii) an engineer having at least a bachelor's degree in mechanical engineering, biomedical engineering, materials science, or another similar engineering field, with experience in the design of and requirements for implantable medical devices.

3. Prior to the late 1980s, abdominal aortic aneurysms (AAA) were repaired surgically. In the most commonly used procedure, a graft material is surgically sewn into the patient's vessels such that the graft replaces the vessel structure to exclude the aneurysm from within. This is a massively invasive and time-consuming procedure, which can lead to complications during the procedure, and the recovery is often long and difficult to manage for the patient. Surgical repair of AAA continues today, but patients obviously desire less invasive procedures that provide the same clinical results.

4. It is generally recognized that the first minimally invasive procedure using catheters for AAA repair was performed by Dr. Juan Parodi in the late 1980s. *See* Juan C. Parodi, *Endovascular Repair of Aortic Aneurysms*, 1 ADVANCES IN VASCULAR SURGERY 85 (1993), attached as Exhibit B. Dr. Parodi used a straight stent-graft tube delivered through a

catheter. Balloon expandable stents were used to fix the graft to the vessel wall. Radiopaque wires were used to correct twisting of the straight tube. One of the problems with Dr. Parodi's design was that patients' aneurysms did not often present an ideal case allowing for neatly securing the proximal and distal ends of the straight tube in the straight section of the aorta, as shown in below.

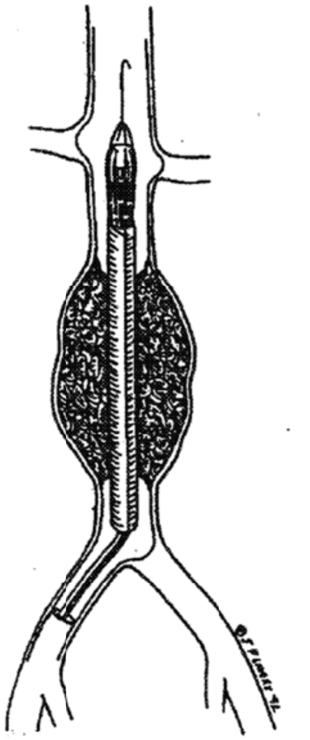


FIGURE 7.
After removal of the sheath, the balloon is positioned for deployment of the stent.

Parodi, *supra*, at 93.

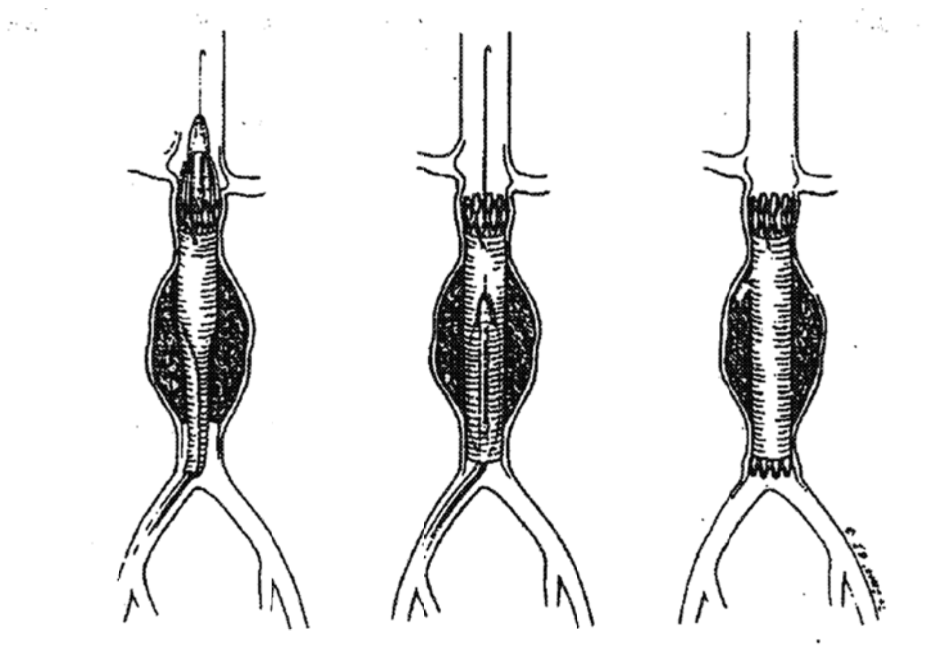


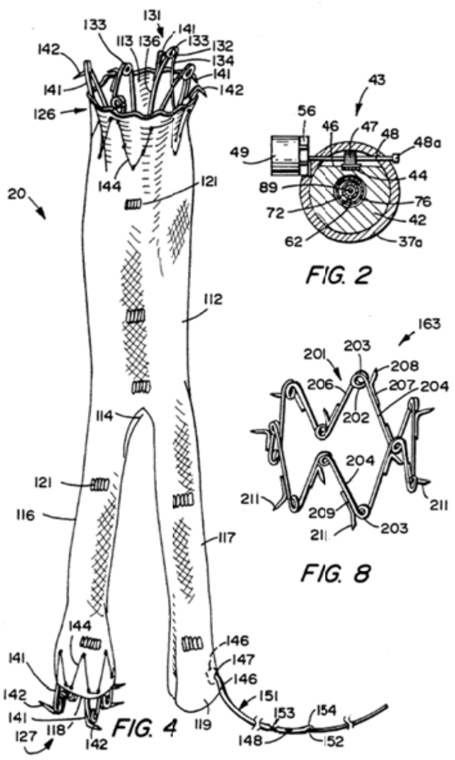
FIGURE 8.
An illustration of the three components of our clinical procedure: proximal stent deployment, distention of the graft, and placement of the distal stent.

Id.

5. In many cases an aneurysm extends into the iliac arteries, the two branched vessels shown at the bottom of the figures above. To treat such patients with Dr. Parodi's technology required attempts to extend a longer straight-tube stent graft down to one of the iliac arteries, and a surgical procedure to connect the now-blocked contralateral iliac artery to a healthy portion of the other iliac artery below (distal to) the end of the stent graft to restore blood flow through both iliac arteries.

6. The technology described in the '102 and '295 Patents reflects the innovations of engineers at EndoVascular Technologies directed to a bifurcated graft device resembling a pair of pants and taking the shape of the descending-Y aorta. A self expandable stent secures the open end of the graft within the aorta and above the aneurysm and a second self expandable stent secures one of the legs of the graft to one of the iliacs. While the inclusion of the self expandable stents provides for a reasonably reliable means of securing attachment of the graft to

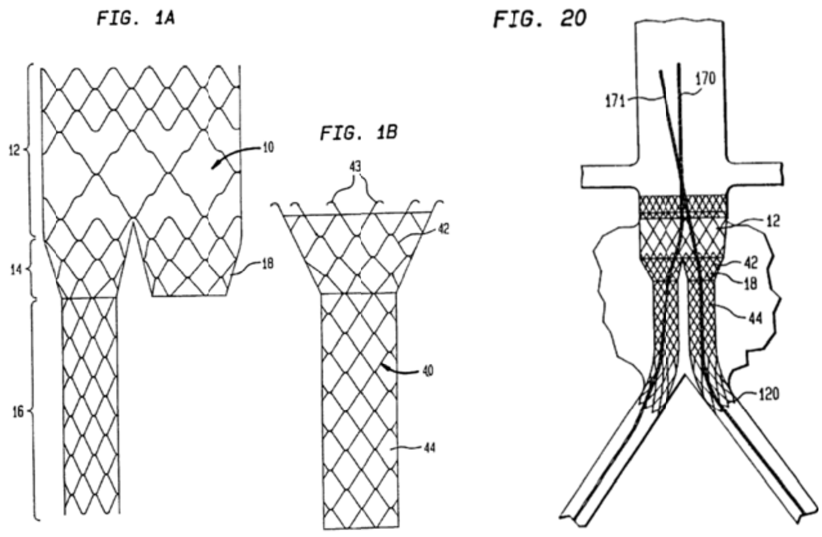
the vessels, the deployment technique to unfurl the otherwise-unsupported graft material and adequately feed the two legs of graft material into the iliac arteries presented challenges in the clinic. An illustrative embodiment of this invention is shown below.



’295 Patent, Tab 1, A4 at fig. 4.

7. The technology described and claimed in the ’020, ’906, ’482, ’724, ’365, ’167, and ’213 Patents reflects the innovations of Dr. Goicoechea and his team at Mintec, along with Drs. Michael Dake and Andrew Cragg, who, in the view of many in the field, revolutionized minimally invasive repair of AAA. The group developed a modular stent graft system comprising a bifurcated stent graft and leg components that can be effectively assembled in the patient’s body. The bifurcated trunk portion is fully supported by a stent and deployed within the aorta. A fully stented leg graft is joined to one of the deployed branches of the trunk by feeding a wire through the contralateral iliac artery. As a constraint on the leg stent-graft is

removed, the self expanding stent of the leg engages the branch of the trunk to secure the leg extension within the trunk. More than twenty years later, this modular system remains the gold standard for the minimally invasive treatment of patients needing AAA repair. An illustrative embodiment of this invention is shown below.



’020 Patent, Tab 36, A530 at figs. 1A, 1B; A544 at fig. 20.

8. While others subsequently filed for patents in 1994 directed to modular systems for AAA repair, it was only Dr. Goicoechea and members of his team who recognized the importance of controlling and adjusting the rotational orientation of the trunk during deployment. They taught in the patents that it is important to rotate the trunk so that the modular components are properly aligned during their assembly together. It is critically important to provide for secure engagement of the modular components to each other for a variety of reasons (including to avoid leaks, stabilize the structure, and minimize the risk of migration), and only Dr. Goicoechea and members of Mintec saw the importance of this innovation. They taught the placement of radiographic indicia having a different radiopacity from the rest of the stent-graft device to create a predictable composite image on an imaging device such that the composite

image changes as the trunk is rotated during the deployment procedure. When the composite image reflects a desired predetermined shape, the clinician has the confidence to know that the modular components are in the correct positions to be fully deployed.

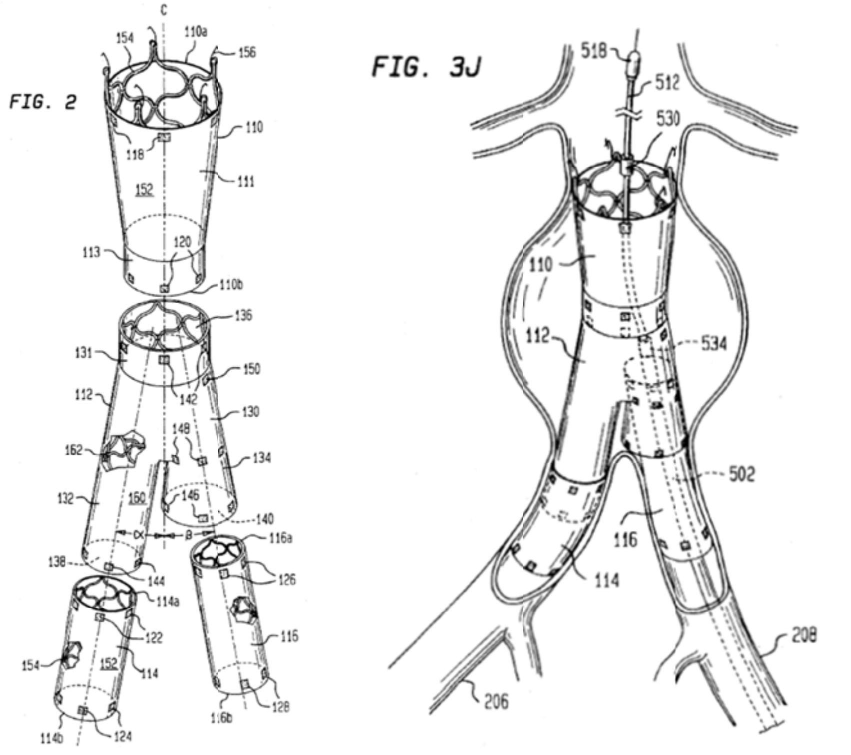
9. In order to provide a more secure engagement of the stent-graft device with the aortic wall, engineers at Endovascular Technologies developed a novel anchoring assembly featuring a sinusoidal wire frame with a series of apices that create an outwardly directed bias to cause the wire frame to spring open from a compressed state upon deployment of the stent-graft. V-shaped members can optionally be provided on the frame, which are responsive to the outwardly directed bias such that the members penetrate the vessel wall to firmly anchor the end of the stent-graft into contact with the vessel. This technology is described and claimed in the ’102 and ’295 Patents.

10. The patents-in-suit also cover innovative deployment technology to deliver a compressed stent-graft to the placement site and deploy it in a reliable manner featuring sheaths and catheters. A pusher cooperates with the stent graft to create a force to hold the stent graft in position during deployment. This technology is described and claimed in the ’906 Patent.

11. The ‘083 Patent describes an innovative system comprising a graft, a compressible attachment system, and a delivery catheter with a releasing system having a tie to retain the stent-graft in the compressed state. When the restraining force of the tie is released, the graft springs open and is held in place by the attachment system. The tie is configured to remain permanently in the vessel with the graft after the delivery system is removed.

12. The technology described and claimed in the ’696 and ’481 Patents reflect the innovations of engineers at Intervascular, Inc., directed to the design of an additional, tubular stent graft component above the proximal (closest to the heart) opening of the stent-graft

system's trunk to secure the trunk in the aorta. Neither Dr. Goicoechea's team nor the other groups working on modular AAA stent-graft systems in 1994 saw the need for this advancement in innovative modular AAA technology. An illustrative embodiment of this invention is shown below.



'696 Patent, Tab 10, A101 and A106 at figs. 2, 3J.

13. Finally, an inventor at the Schneider Company developed an innovative technology to prevent leakage of fluid through the stent graft itself, which he filed for a patent in 1998. If fluid leaks through a stent-graft it can cause an undesirable mixing of different body fluids in the case where fluid flows from outside to inside the stent graft tube, or where fluid flows from inside to outside the stent graft tube. If the stent graft is used to isolate an aneurysm, leakage of fluid out of the stent graft and into contact with the aneurysm sac can result in a failure to isolate the sac from arterial pressure, and cause it to rupture. The engineer at Schneider

developed a stent-graft design where the layers of the stent graft can be selected such that one of the layers has an average permeability that is less than the average permeability of a second layer. This technology is described and claimed in the ’064 Patent.

II. ’083 PATENT

14. I have reviewed the specification and claims of the ’083 Patent. I have also reviewed the parties’ competing constructions of each term identified for construction.

A. *“attachment system”*

15. I understand that means-plus-function claiming applies only to purely functional limitations that do not provide the structure that performs the recited function. I further understand that the failure to use the term “means” gives rise to a presumption that a limitation is not a means-plus-function limitation.

16. One of skill in the art would not understand “attachment system” to be a means-plus-function limitation. Rather, reading the claim in the context of the ’083 Patent, one of skill in the art would understand that the reference to an “attachment system” connotes structure. The claim’s recital of a “first configuration” that is “compressed” from a “second configuration” signifies structure, as does the claim’s recital that the attachment system is “secured to one of said ends” of the stent-graft system.

III. ’724 PATENT

17. I have reviewed the specification and claims of the ’724 Patent. I have also reviewed the parties’ competing constructions of each term identified for construction.

A. *“a radiopaque marker”*

18. The term “radiopaque marker” is a commonly understood term in the art. The specification describes the use of a marker to determine and adjust rotational orientation of a prosthesis. I understand that Plaintiffs contend the term “a radiopaque marker” should be given

its plain and ordinary meaning while Gore contends that the term should be construed to mean "an individual radiopaque marker." I agree with Plaintiff. The term "radiopaque marker" is well-known in the art and one of ordinary skill in the art would not think it limited to "an individual radiopaque marker" as Gore suggests, particularly since the goal is to determine rotational orientation. A radiopaque marker can refer to a single structure that is radiopaque, such as a gold wire sewn into a graft material. Likewise, a group of more than one such structures, such as two gold wires sewn into a graft material, can collectively be referred to as a radiopaque marker.

19. I have reviewed the claims of the '724 Patent and in my opinion, nothing in the claim language limits the term "a radiopaque marker" as Gore suggests. Claim 1 of the '724 Patent recites that the "radiopaque marker" can be used to "determine the rotational orientation" and "adjust[] the rotational orientation" of the prosthesis via x-ray. Tab 32, A510 at cl. 1. One of skill in the art would not understand the claim language is limited to "an individual radiopaque marker" for either determining or adjusting the rotational orientation. If multiple markers together formed a predetermined shape that, detected via x-ray, could be used to perform the steps of claim 1 of the '724 Patent, a person of ordinary skill in the art would understand those multiple markers forming that predetermined shape to be "a radiopaque marker" in the context of the claim language. What is important considering the context of the claim language is that "a radiopaque marker" has a predetermined shape and the marker is used to determine and adjust the rotational orientation of the prosthesis. There is nothing in the language of the claims to require that "a radiopaque marker" is limited to a single or unitary piece of structure.

20. One of skill in the art would also understand based on the specification that the term "a radiopaque marker" is not limited as Gore suggests. Figure 4(a), an embodiment of the

invention, is described as illustrating a marker made out a single piece of wire formed into a "V." As an alternative, however, Figure 4(a) and the specification describe the use of a radiopaque marker comprised of a radiopaque tube. A single tube embodiment would not reliably indicate the rotational orientation of the prosthesis. One of skill in the art would understand that clinical use of a such a prosthesis could cause serious adverse events that would harm a patient. Accordingly, one of skill in the art would understand that determination of rotation orientation would require more than one tube that together form a predetermined shape, such as a "V", that could be used to determine and/or adjust the rotational orientation of the prosthesis. Moreover, one of ordinary skill in the art would also understand that two wires, rather than the single wire disclosed in Fig. 4a, could be used to make a predetermined shape, such as a "V", that could be used to determine and/or adjust the rotational orientation of the prosthesis.

21. I have studied the prosecution history of the '724 Patent application, including specific reference to an Office Action dated November 5, 1996, and an amendment and remarks dated March 10, 1997, made in response to the Office Action. I have also studied the references discussed therein.

22. U.S. Patent No. 5,562,728 to Lazarus (attached as Exhibit C) teaches adjustment of or torsion of a prosthesis. As shown below, Lazarus discloses a non-bifurcated, straight tube prosthesis.

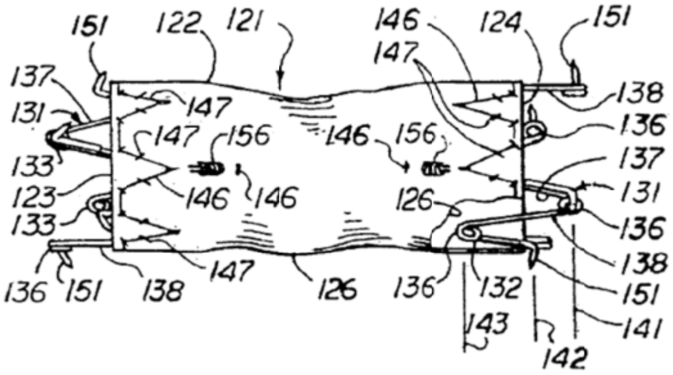


Figure 10 of Lazarus

Lazarus discloses four radiopaque elements, two radiopaque elements at the proximal end of this prosthesis and two at the distal end, used to assess the *relative* twist or torsion of the graft—that is, the twist of the proximal end relative to the distal end. There is no teaching in Lazarus regarding the identification or adjustment of the rotational orientation of the whole prosthesis. Moreover, rotational orientation is not relevant to the prosthesis disclosed in Lazarus because it is a straight tube without bifurcation. Only twisting of one end relative to the other is relevant to the invention disclosed in the Lazarus reference. Finally, Lazarus teaches correction of twisting only after the proximal end of the prosthesis has been deployed, including deployment of proximal hooks into the vessel wall. Once partially deployed in this manner, it is not possible to adjust the rotational orientation of the whole stent-graft without damaging the vessel wall and potentially putting the patient's life in danger.

23. U.S. Patent No. 5,562,726 to Chuter (attached as Exhibit D) discloses radiopaque markers on the legs of a bifurcated stent graft, but Chuter does not teach how the markers are used. Specifically, as shown below, Chuter discloses lines, 211 and 212, and markers, 214, and 215, placed on each of the legs of the prosthesis.

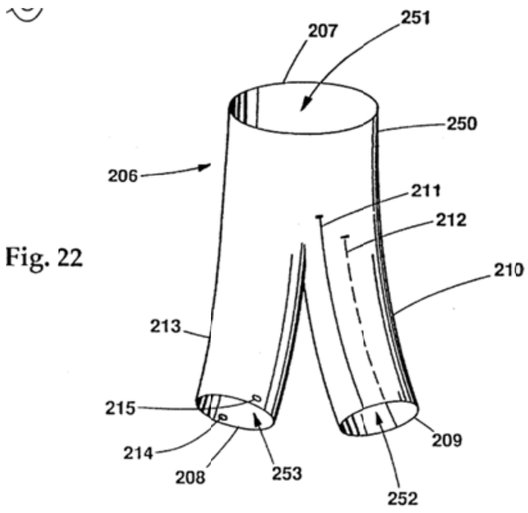


Figure 22 of Chuter

The patentee in the prosecution history hypothesized that these markers may be used to identify and correct twisting or torsion of the legs of the bifurcated stent graft. One of skill in the art, however, would understand that any such hypothesis is unsupportable and wrong. The Chuter graft is deployed and fixed into position by expanding the main body 250 and the ispilateral leg 213. At this point, the rotational orientation of the stent-graft is set, and cannot be changed without great risk to the patient. Following the setting of the main body and ipsilateral leg, the radiopaque lines 211 and 212 are only used to detect twisting of the contralateral leg 210 as it is deployed (essentially in the same manner that Lazarus' markers are used to avoid deploying a twisted graft).

24. U.S. Patent No. 5,489,295 to Piplani (attached as Exhibit E) provides no teaching as to how radiopaque markers on the prosthesis are to be used.

IV. ’213, ’020, ’167, AND ’906 PATENTS

25. I understand that Gore has raised an argument that apparatus claims 1 and 9 of the ’213 Patent, claim 5 of the ’020 Patent, claims 16 and 18 of the ’906 Patent, and claim 63 of the ’167 Patent require an actor, such as a physician, to perform a method step in order to meet the

claim limitations. I have reviewed these claims, and I don't see anything in any of these claims to suggest that a physician or anyone else must perform a method step to meet the limitations of the claim. Rather, all the claim limitations are directed to the device itself.

V. ’064 PATENT

26. I have reviewed the specification and claims of the ’064 Patent. I have also reviewed the Parties' competing constructions of each term identified for construction.

27. I understand there is a dispute regarding whether a tubular mesh structure, mesh structure, or structural mesh layer must be a stent formed of a crossing pattern of wires. I believe one of ordinary skill in the art would understand the term mesh to be broader, in that it does not require a crossing pattern of wires. The purpose of the mesh is to provide structure. Many stent structures with mesh embodiments are known in the art that do not include crossing of wires, including laser-cut tubes. The Palmaz-Shatz stent, which was laser-cut and did not have crossing wires, was one of the most widely used stents in the world in the 1990s, and people in the field routinely referred to the stent as a mesh. *See, e.g.*, C. Janicki, et al, *Radiation dose from a phosphorous-32 impregnated wire mesh vascular stent*, 24 MEDICAL PHYSICS 3 (March 1997), attached as Exhibit F.

28. I have been asked to consider whether the term “average permeability” would be understood by a person of ordinary skill to require use of a specific test method to make the determination whether a prostheses has a first graft layer having a first average permeability and a membrane layer having a second average permeability, and the permeability of the membrane layer is less than the permeability of the graft layer. I have studied the ’064 Patent specification and claims. In my opinion, one skilled in the art, given the information in the specification of the ’064 Patent, could readily design a stent graft that falls within the scope of the asserted claims without conducting any testing to determine the exact permeabilities of each individual layer.

The specification of the ’064 Patent does not require a test to determine the permeabilities of the graft layer and the membrane layer. The specification mentions recommended ranges for the permeabilities of the respective layers, and these ranges reflect that the recommended permeability of the membrane is less than the recommended permeability of the graft.

29. The specification describes a prosthesis “configured such that at least one of the outside layers is substantially impermeable to a fluid and substantially separates a first body fluid located outside the endoprosthesis from a second body fluid located in the passage [tube].” Tab 37, A577 at 5:5-8. To achieve this design goal, the patent teaches and the claims recite layering of a graft material and a membrane where the graft has a first permeability and the membrane has a second permeability less than the permeability of the graft layer. The specification teaches that one skilled in the art can select a graft layer from a list of known materials such as polyethylene terephthalate (PET) and expanded polytetrafluoroethylene (ePTFE) and one skilled in the art can select a membrane layer from a list of known materials such as silicone elastomer or a polymer that is resistant to fluid permeability. Tab 37, A576 at 3:44–50. One skilled in the art would be familiar with the relative permeabilities of these materials named (and others) for the graft layer and the membrane layer, and would be able to select both a graft layer and a less permeable membrane to achieve the design goal.

30. To the extent testing was necessary to design a stent graft with a membrane of less permeability than the graft layer, one skilled in the art could readily develop tests to determine the relative permeabilities of the layers. Tests for material permeability date back for more than one hundred years.

31. I understand Gore contends the permeability of the prosthesis must be measured by a test method described in ISO 7198:1998, attached hereto as Exhibit G. I disagree. The ISO

7198 test itself indicates that it is a "voluntary standard" with "recommended practices." It sets forth general, but not specific, guidelines for how to test certain types of vascular prostheses. The document further states the "recommendations do not purport to comprise a complete test program," (Tab 57, A1085) which implies some guidelines for tests are provided, but there may be other tests that are relevant.

32. The ISO 7198 test is a water permeability test. Blood is essentially water plus a large amount of cells, proteins, etc. (approximately 50% by volume), and these components will make the fluid as a whole less likely to pass through small passages than just water alone. Blood serum is blood from which cellular components and substances important for clotting have been removed. The remaining components (other proteins, etc.) give serum a higher viscosity than water alone. So one skilled in the art would expect permeability values to be lower for blood (or serum) than for water.

VI. ’295 PATENT

33. I have reviewed the specification and claims of the ’295 Patent. I have also reviewed the parties’ competing constructions of each term identified for construction.

A. *"first" and "second expandable attachment means"*

34. I understand that the parties have agreed that the function for these terms includes "anchoring the main body" and "anchoring the first tubular leg," and that Gore and Endologix contend the functions include further limitations on where the anchoring occurs. My opinion, as set out below, would be the same for either function.

35. The specification describes a preferred embodiment of a self expandable spring as including the helical coil springs (item 133 in Figure 4, Tab 1, A4), but there is nothing in the specification to indicate that those helical coil springs are necessary to perform the function. The specification describes expandable spring attachment means 126, and that these expandable

springs serve to anchor and secure the graft within the vessel wall. ’295 Patent, Tab 1, A11 at 5:29–35. One skilled in the art would understand that a self expandable spring is all the structure that is necessary to perform the function.

36. The specification describes a preferred embodiment of a self expandable spring as including hook-like elements that penetrate the vessel wall. See ’295 Patent, Tab 1, A11 at 5:59–67. One of skill in the art at the time of the invention in 1993, however, would understand that such hooks are not necessary to perform the claimed “anchoring” function. Rather, one of skill in the art at the time would have understood that a form-fitting circumferential engagement with the vessel wall provided by a self expandable spring would be sufficient to perform the claimed “anchoring” function.

B. *“support means”*

37. I understand that the parties have agreed that the function for these terms is “reinforcing the aortic bifurcation proximate the aneurysm to prevent rupture.”

38. I have analyzed the specification of the ’295 Patent to determine the structure necessary for performing that function. I have determined that the structure necessary to perform the function is, in the words of the ’295 Patent, a bifurcated graft.

39. The specification describes “graft 20 having a bifurcation.” ’295 Patent, Tab 1, A9 at 2:60–61. This is the structure that is necessary to perform the function recited in the claim.

C. *“marker means”*

40. I understand that the parties have essentially agreed that the function for these terms is “positioning said support means in the aortic bifurcation relative to the aneurysm.”

41. I have analyzed the specification of the ’295 Patent to determine the structure necessary for performing that function. I have determined that the structure necessary to perform the function is, in the words of the ’295 Patent, radiopaque markers.

42. The specification describes "radiopaque markers 121." '295 Patent, Tab 1, A11 at 5:24. Nothing in the specification requires that the markers be on the main body and the legs.

43. The '295 Patent describes lengths of platinum wire secured by Dacron sutures as an example of radiopaque markers. One of skill in the art would understand that these particular elements are examples, and that radiopaque markers may be constructed of other materials, such as gold, or secured in other ways. *See* '295 Patent, Tab 1, A11 at 5:26–28.

VII. '481 PATENT

44. I have reviewed the specification and claims of the '481 Patent. I have also reviewed the parties' competing constructions of each term identified for construction.

A. *"dividing means"*

45. I understand that the parties have agreed that the function for this term is "forming first and second passageways communicating between said proximal and distal ends."

46. I have analyzed the specification of the '481 Patent to determine the structure necessary for performing that function. I have determined that the specification discloses four different structures to perform the function: (1) a Y-shaped graft or Y-shaped stent forming a crotch; (2) a web; (3) graft material stitched to form two channels; or (4) two tubes.

47. The first of these embodiments is straight-forward, although Gore and Endologix have excluded it from their constructions. The specification discloses base member 112, which is a Y-shaped structure that "branches into two legs" at a "crotch area," and is shown in Figures 1 and 2. '481 Patent, Tab 11, A141 at 10:33–35, 53; A126-127 at figs. 1–2. The specification also refers to this configuration as "integrally formed legs." '481 Patent, Tab 11, A146 at 19:5–6. One of skill in the art would readily understand that crotch creating Y-shaped integrally formed legs is structure for the "dividing means" in the '481 Patent claims.

48. The specification describes an alternative embodiment in which the main body is "divided into two portions 606 and 608 by a web 610." '481 Patent, Tab 11, A146 at 19:15–16; A134 at fig. 5.

49. The specification further describes an alternative embodiment in which the two channels are formed by a "stitch line joining the outer layer 708 on the diametrically opposed surfaces of base member 700 to define two tubular channels 710 and 712." '481 Patent, Tab 11, A146 at 20:65–67; A135 at fig. 7.

50. The specification further describes an alternative embodiment in which the two channels are formed of two "tubes . . . which are independent of one another." '481 Patent, Tab 11, A147 at 21:19–21.

51. Each of these structures performs the function of "forming first and second passageways communicating between said proximal and distal ends."

B. *"joining means," "connecting means," "attaching means"*

52. I understand that the parties have agreed that the functions for each of these terms are similar: for the "joining means," the function is "intraluminally joining said distal end of said primary limb to said proximal end of said base member"; for the "connecting means," the function is "connecting the proximal end of the secondary limb to the distal end of the base member;" and for the "attaching means," the function is "attaching the proximal end of another secondary limb to the distal end of the base member."

53. I have analyzed the specification of the '481 Patent to determine the structure necessary for performing the agreed functions recited in Paragraph ¶ 52. I have determined that the structure necessary to perform each function is an expandable stent and graft material. '481 Patent, Tab 11, A142 at 11:60 to 12:7.

54. The specification describes "flexible outer layer 152" (a graft), which is "supported internally along substantially its entire length by an expandable stent 154." '481 Patent, Tab 11, A142 at 11:60 to 12:7. One of skill in the art would understand that the disclosed stent and graft material perform the agreed functions. Specifically, the expandable stent and graft material of the primary limb and the expandable stent and graft material of the base member perform the agreed function of the "joining means." The expandable stent and graft material of the secondary limb and the expandable stent and graft material of the base member perform the agreed function of the "connecting means." Finally, the expandable stent and graft material of the recited "another secondary limb" and the expandable stent and graft material of the base member perform the agreed function of the "attaching means."

55. One of skill in the art in 1995 would understand that the stent as disclosed could take many shapes and forms, and still properly perform the agreed functions by providing "sufficient structural strength" to the graft material. '481 Patent, Tab 11, A142 at 11:66.

VIII. '906 PATENT

56. I have reviewed the specification and claims of the '906 Patent. I have also reviewed the parties' competing constructions of each term identified for construction.

A. *"portion adapted for connection," claim 11*

57. The reference to a "portion adapted for connection to another prosthesis" in claim 11 connotes structure to one of skill in the art. This is particularly evident when viewed together with the rest of the language of claim 11, which recites that a "second prosthesis" is introduced in a "radially compressed state . . . into said portion of said first prosthesis," and that the second prosthesis is deployed "to connect to said portion of said first prosthesis and to define said continuous lumen through said first prosthesis and said second prosthesis." Tab 17, A290 at cl. 11.

B. *“first introducer,” “second introducer,” claim 11*

58. Claim 11 is directed to a “system for delivering a prosthesis into the vasculature of a body,” that is, an endoluminal prosthesis. One of skill in the art would understand that the term “introducer” refers to a system commonly used in the field to introduce an endoluminal prosthesis into the vasculature, and potentially to deploy it as well. Although an introducer can be designed in any number of ways, a typical introducer includes an outer sheath, a tube or pusher to move the endoprosthesis into position, seals and valves to prevent blood leakage, and one or more handles to control positioning and deployment of the endoprosthesis.

59. One of skill in the art would understand the term “introducer,” in the context of an endoluminal prosthesis, to describe structure.

I hereby declare and swear that the statements herein are truthful and accurate under the penalty of perjury.

DATED: April 6, 2015

____
Dr. James Moore, Jr.